

AMENDED IN ASSEMBLY JANUARY 13, 2016

AMENDED IN ASSEMBLY JANUARY 5, 2016

AMENDED IN ASSEMBLY JANUARY 4, 2016

AMENDED IN ASSEMBLY APRIL 16, 2015

AMENDED IN ASSEMBLY MARCH 26, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 1386

Introduced by Assembly Member Low

February 27, 2015

An act to add Section 4119.4 to the Business and Professions Code, to amend Section 1714.23 of the Civil Code, and to amend Section 1797.197a of the Health and Safety Code, relating to emergency medical care.

LEGISLATIVE COUNSEL'S DIGEST

AB 1386, as amended, Low. Emergency medical care: epinephrine auto-injectors.

(1) Existing law authorizes a prehospital emergency medical care person, first responder, or lay rescuer to use an epinephrine auto-injector to render emergency care to another person, as specified. Existing law requires the Emergency Medical Services Authority to approve authorized training providers and the minimum standards for training and the use and administration of epinephrine auto-injectors. The existing Pharmacy Law, *Law* also authorizes a pharmacy to dispense epinephrine auto-injectors to a prehospital emergency medical care person, first responder, or lay rescuer for the purpose of rendering

emergency care in accordance with these provisions. A violation of the Pharmacy Law is a crime.

This bill would permit an “authorized entity,” as defined, to use an epinephrine auto-injector to render emergency care to another person in accordance with these provisions. The bill would also authorize a pharmacy to furnish epinephrine auto-injectors to an authorized ~~entity pursuant to those provisions~~ *entity, as provided*. Because a violation of these provisions would be a crime, the bill would impose a state-mandated local program. The bill would require an authorized entity to create and maintain a specified operations plan relating to its use of epinephrine auto-injectors, and would require those entities to submit a report to the State Department of Public Health on incidents related to the administration of epinephrine auto-injectors. The bill would also require the department to issue an annual report summarizing and analyzing the reports submitted to the department pursuant to the bill’s provisions.

(2) Under existing law, everyone is generally responsible, not only for the result of his or her willful acts, but also for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person, except so far as the latter has, willfully or by want of ordinary care, brought the injury upon himself or herself. Existing law also provides that a prehospital emergency care person, first responder, or lay rescuer who administers an epinephrine auto-injector to another person who appears to be experiencing anaphylaxis at the scene of an emergency situation, in good faith and not for compensation, is not liable for any civil damages resulting from his or her acts or omissions in administering the epinephrine auto-injector, if that person has complied with specified certification and training requirements and standards.

This bill would provide that ~~any employee, agent, or other trained individual of an authorized entity who administers an epinephrine auto-injector to another person who appears to be experiencing anaphylaxis at the scene of an emergency situation, in good faith and not for compensation, is not liable for any civil damages resulting from his or her acts or omissions in administering the epinephrine auto-injector, if that person has complied with specified certification and training requirements and standards.~~ The bill would also provide that an authorized entity is not liable for any civil damages resulting from any act or omission connected to the administration of an epinephrine auto-injector, as specified.

(3)The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 4119.4 is added to the Business and
2 Professions Code, to read:

3 4119.4. (a) Notwithstanding any other law, a pharmacy may
4 furnish epinephrine auto-injectors to an authorized entity, as
5 defined by Section 1797.197a of the Health and Safety Code, if
6 both of the following requirements are met:

7 (1) The epinephrine auto-injectors are furnished exclusively for
8 ~~the possession of an authorized entity and for use by its employees,~~
9 ~~volunteers, and agents, first responder, or by a family member or~~
10 ~~caregiver of the person who appears to be experiencing~~
11 ~~anaphylaxis, as defined by paragraph (1) of subdivision (a) of~~
12 ~~Section 1714.23 of the Civil Code, or by the person who appears~~
13 ~~to be experiencing anaphylaxis, as defined by paragraph (1) of~~
14 ~~subdivision (a) of Section 1714.23 of the Civil Code. use by, or~~
15 ~~in connection with, an authorized entity.~~

16 (2) An authorized health care provider provides a prescription
17 that specifies the quantity of epinephrine auto-injectors to be
18 furnished.

19 (b) The pharmacy shall label each epinephrine auto-injector
20 dispensed with all of the following:

21 (1) The name of the person or entity to whom the prescription
22 was issued.

23 (2) The designations “Section 1797.197a Responder” and “First
24 Aid Purposes Only.”

25 (3) The dosage, use, and expiration date.

26 (c) Each dispensed prescription shall include the manufacturer’s
27 product information sheet for the epinephrine auto-injector.

28 (d) Records regarding the acquisition and disposition of
29 epinephrine auto-injectors furnished pursuant to subdivision (a)
30 shall be maintained by the authorized entity for a period of three

1 years from the date the records were created. The authorized entity
2 shall be responsible for monitoring the supply of epinephrine
3 auto-injectors and ensuring the destruction of expired epinephrine
4 auto-injectors.

5 (e) The epinephrine auto-injector dispensed pursuant to this
6 section may be used only for the purpose, and under the
7 circumstances, described in Section 1797.197a of the Health and
8 Safety Code.

9 SEC. 2. Section 1714.23 of the Civil Code is amended to read:

10 1714.23. (a) For purposes of this section, the following
11 definitions shall apply:

12 (1) “Anaphylaxis” means a potentially life-threatening
13 hypersensitivity or allergic reaction to a substance.

14 (A) Symptoms of anaphylaxis may include shortness of breath,
15 wheezing, difficulty breathing, difficulty talking or swallowing,
16 hives, itching, swelling, shock, or asthma.

17 (B) Causes of anaphylaxis may include, but are not limited to,
18 insect stings or bites, foods, drugs, and other allergens, as well as
19 idiopathic or exercise-induced anaphylaxis.

20 (2) “Epinephrine auto-injector” means a disposable drug delivery
21 system with a spring-activated concealed needle that is designed
22 for emergency administration of epinephrine to provide rapid,
23 convenient first aid for persons suffering from anaphylaxis.

24 (b) (1) Any person described in subdivision (b) of Section
25 1797.197a of the Health and Safety Code who administers an
26 epinephrine auto-injector, in good faith and not for compensation,
27 to another person who appears to be experiencing anaphylaxis at
28 the scene of an emergency situation is not liable for any civil
29 damages resulting from his or her acts or omissions in
30 administering the epinephrine auto-injector, if that person has
31 complied with the requirements and standards of Section 1797.197a
32 of the Health and Safety Code.

33 ~~(2) An authorized health care provider that prescribes or~~
34 ~~dispenses an epinephrine auto-injector to a person described in~~
35 ~~subdivision (b) of Section 1797.197a of the Health and Safety~~
36 ~~Code or an authorized entity is not liable for any civil damages~~
37 ~~resulting from any act or omission related to the provision of an~~
38 ~~epinephrine auto-injector.~~

39 (3) ~~A person that conducts the training described in subdivision~~
40 ~~(e) of Section 1797.197a of the Health and Safety Code is not~~

1 liable for any civil damages resulting from any act or omission of
2 the lay rescuer, as defined by paragraph (4) of subdivision (a) of
3 Section 1797.197a of the Health and Safety Code, who renders
4 emergency care by administering the epinephrine auto-injector.

5 ~~(4)~~

6 (2) (A) An authorized entity shall not be ~~liable~~, *liable* for any
7 civil damages resulting from any act or omission other than an act
8 or omission constituting gross negligence or willful or wanton
9 misconduct connected to the administration of an epinephrine
10 auto-injector by any one of its employees, volunteers, or agents
11 who is a lay rescuer, as defined by paragraph (4) of subdivision
12 (a) of Section 1797.197a of the Health and Safety Code, ~~or who,~~
13 ~~in good faith, and not for compensation, renders emergency~~
14 ~~medical or nonmedical care at the scene of an emergency. Code.~~

15 (B) The failure of an authorized entity to possess or administer
16 an epinephrine auto-injector shall not result in civil liability.

17 ~~(5)~~

18 (3) This subdivision does not affect any other immunity or
19 defense that is available under law, ~~including, but not limited to,~~
20 ~~the immunity from liability for any civil damages resulting from~~
21 ~~any act or omission other than an act or omission constituting gross~~
22 ~~negligence or willful or wanton misconduct of a person who in~~
23 ~~good faith, and not for compensation, renders emergency medical~~
24 ~~or nonmedical care at the scene of an emergency as provided by~~
25 ~~section 1799.102 of the Health and Safety Code. law.~~

26 (c) The protection specified in subdivision (b) shall not apply
27 in a case of personal injury or wrongful death that results from the
28 gross negligence or willful or wanton misconduct of the person
29 who renders emergency care treatment by the use of an epinephrine
30 auto-injector.

31 (d) Nothing in this section relieves a manufacturer, designer,
32 developer, distributor, or supplier of an epinephrine auto-injector
33 of liability under any other applicable law.

34 SEC. 3. Section 1797.197a of the Health and Safety Code is
35 amended to read:

36 1797.197a. (a) For purposes of this section, the following
37 definitions shall apply:

38 (1) “Anaphylaxis” means a potentially life-threatening
39 hypersensitivity or allergic reaction to a substance.

1 (A) Symptoms of anaphylaxis may include shortness of breath,
2 wheezing, difficulty breathing, difficulty talking or swallowing,
3 hives, itching, swelling, shock, or asthma.

4 (B) Causes of anaphylaxis may include, but are not limited to,
5 insect stings or bites, foods, drugs, and other allergens, as well as
6 idiopathic or exercise-induced anaphylaxis.

7 (2) “Authorized entity” means any for-profit, nonprofit, or
8 government entity or organization that employs at least one person
9 or utilizes at least one volunteer or agent that has voluntarily
10 completed a training course as described in subdivision (c).

11 (3) “Epinephrine auto-injector” means a disposable drug delivery
12 system with a spring-activated concealed needle that is designed
13 for emergency administration of epinephrine to provide rapid,
14 convenient first aid for persons suffering from anaphylaxis.

15 (4) “Lay rescuer” means any person who has met the training
16 standards and other requirements of this section but who is not
17 otherwise licensed or certified to use an epinephrine auto-injector
18 on another person.

19 (5) “Prehospital emergency medical care person” has the same
20 meaning as defined in paragraph (2) of subdivision (a) of Section
21 1797.189.

22 (b) A prehospital emergency medical care person or lay rescuer
23 may use an epinephrine auto-injector to render emergency care to
24 another person if all of the following requirements are met:

25 (1) The epinephrine auto-injector is legally obtained by
26 prescription from an authorized health care provider or from an
27 authorized entity that acquired the epinephrine auto-injector
28 pursuant to subdivision (e). ~~An authorized health care provider
29 may issue a prescription for an epinephrine auto-injector to a person
30 described in this subdivision for the purpose of rendering
31 emergency care to another person, upon presentation of current
32 certification demonstrating that person is trained and qualified to
33 administer an epinephrine auto-injector as a prehospital emergency
34 medical care person or lay rescuer, pursuant to this section or any
35 other statute or regulation.~~

36 (2) The epinephrine auto-injector is used on another, with the
37 expressed or implied consent of that person, to treat anaphylaxis.

38 (3) The epinephrine auto-injector is stored and maintained as
39 directed by the manufacturer’s instructions for that product.

1 (4) The person using the epinephrine auto-injector has
2 successfully completed a course of training with an authorized
3 training provider, as described in subdivision (c), and has current
4 certification of training issued by the provider.

5 (5) The epinephrine auto-injectors obtained by prehospital
6 emergency medical care personnel pursuant to Section 4119.3 of
7 the Business and Professions Code shall be used only when
8 functioning outside the course of the person's occupational duties,
9 or as a volunteer, pursuant to this section.

10 (6) The Emergency Medical Services System is activated as
11 soon as practicable when an epinephrine auto-injector is used.

12 (c) (1) The authorized training providers shall be approved,
13 and the minimum standards for training and the use and
14 administration of epinephrine auto-injectors pursuant to this section
15 shall be established and approved, by the authority. The authority
16 may designate existing training standards for the use and
17 administration of epinephrine auto-injectors by prehospital
18 emergency medical care personnel to satisfy the requirements of
19 this section.

20 (2) The minimum training and requirements shall include all of
21 the following components:

22 (A) Techniques for recognizing circumstances, signs, and
23 symptoms of anaphylaxis.

24 (B) Standards and procedures for proper storage and emergency
25 use of epinephrine auto-injectors.

26 (C) Emergency followup procedures, including activation of
27 the Emergency Medical Services System, by calling the emergency
28 9-1-1 telephone number or otherwise alerting and summoning
29 more advanced medical personnel and services.

30 (D) Compliance with all regulations governing the training,
31 indications, use, and precautions concerning epinephrine
32 auto-injectors.

33 (E) Written material covering the information required under
34 this provision, including the manufacturer product information
35 sheets on commonly available models of epinephrine auto-injectors.

36 (F) Completion of a training course in cardiopulmonary
37 resuscitation and the use of an automatic external defibrillator
38 (AED) for infants, children, and adults that complies with
39 regulations adopted by the authority and the standards of the

1 American Heart Association or the American Red Cross, and a
2 current certification for that training.

3 (3) Training certification shall be valid for no more than two
4 years, after which recertification with an authorized training
5 provider is required.

6 (4) The director may, in accordance with regulations adopted
7 by the authority, deny, suspend, or revoke any approval issued
8 under this subdivision or may place any approved training provider
9 on probation upon a finding by the director of an imminent threat
10 to public health and safety, as evidenced by any of the following:

11 (A) Fraud.

12 (B) Incompetence.

13 (C) The commission of any fraudulent, dishonest, or corrupt
14 act that is substantially related to the qualifications, functions, or
15 duties of training program directors or instructors.

16 (D) Conviction of any crime that is substantially related to the
17 qualifications, functions, or duties of training program directors
18 or instructors. The record of conviction or a certified copy of the
19 record shall be conclusive evidence of the conviction.

20 (E) Violating or attempting to violate, directly or indirectly, or
21 assisting in or abetting the violation of, or conspiring to violate,
22 any provision of this section or the regulations promulgated by the
23 authority pertaining to the review and approval of training
24 programs in anaphylaxis and the use and administration of
25 epinephrine auto-injectors, as described in this subdivision.

26 (d) (1) The authority shall assess a fee pursuant to regulation
27 sufficient to cover the reasonable costs incurred by the authority
28 for the ongoing review and approval of training and certification
29 under subdivision (c).

30 (2) The fees shall be deposited in the Specialized First Aid
31 Training Program Approval Fund, which is hereby created in the
32 State Treasury. All moneys deposited in the fund shall be made
33 available, upon appropriation, to the authority for purposes
34 described in paragraph (1).

35 (3) The authority may transfer unused portions of the Specialized
36 First Aid Training Program Approval Fund to the Surplus Money
37 Investment Fund. Funds transferred to the Surplus Money
38 Investment Fund shall be placed in a separate trust account, and
39 shall be available for transfer to the Specialized First Aid Training

1 Program Approval Fund, together with the interest earned, when
2 requested by the authority.

3 (4) The authority shall maintain a reserve balance in the
4 Specialized First Aid Training Program Approval Fund of 5 percent
5 of annual revenues. Any increase in the fees deposited in the
6 Specialized First Aid Training Program Approval Fund shall be
7 effective upon determination by the authority that additional
8 moneys are required to fund expenditures pursuant to subdivision
9 (c).

10 ~~(e) An authorized health care provider may prescribe epinephrine
11 auto-injectors to an authorized entity. Epinephrine auto-injectors
12 acquired by an authorized entity shall be stored in a location readily
13 accessible in an emergency and in accordance with the epinephrine
14 auto-injectors instructions for use and any additional requirements
15 that may be established by the authority.~~

16 *(e) (1) An authorized health care provider may issue a
17 prescription for an epinephrine auto-injector to a prehospital
18 emergency medical care person or a lay rescuer for the purpose
19 of rendering emergency care to another person upon presentation
20 of a current certification demonstrating that the person is trained
21 and qualified to administer an epinephrine auto-injector pursuant
22 to this section or any other law.*

23 *(2) An authorized health care provider may issue a prescription
24 for an epinephrine auto-injector to an authorized entity if the
25 authorized entity submits evidence it employs at least one person,
26 or utilizes at least one volunteer or agent, who is trained and
27 qualified to administer an epinephrine auto-injector pursuant to
28 this section.*

29 (f) An authorized entity that possesses and makes available
30 epinephrine auto-injectors shall do both of the following:

31 (1) Create and maintain on its premises an operations plan that
32 includes all of the following:

33 (A) The name and contact number for the authorized health care
34 provider who prescribed the epinephrine auto-injector.

35 (B) Where and how the epinephrine auto-injector will be stored.

36 (C) The names of the designated employees or agents who have
37 completed the training program required by this section and who
38 are authorized to administer the epinephrine auto-injector.

39 (D) How and when the epinephrine auto-injector will be
40 inspected for an expiration date.

1 (E) The process to replace the expired epinephrine auto-injector,
 2 including the proper disposal of the expired epinephrine
 3 ~~auto-injector.~~ *auto-injector or used epinephrine auto-injector in*
 4 *a sharps container.*

5 (2) Submit to the State Department of Public Health, on a form
 6 developed by the State Department of Public Health, a report of
 7 each incident on the authorized entity’s premises that involves the
 8 administration of an epinephrine auto-injector. The State
 9 Department of Public Health shall annually publish a report that
 10 summarizes and analyzes all reports submitted to it under this
 11 subdivision.

12 (g) This section shall not apply to a school district or county
 13 office of education, or its personnel, that provides and utilizes
 14 epinephrine auto-injectors to provide emergency medical aid
 15 pursuant to Section 49414 of the Education Code.

16 (h) This section shall not be construed to limit or restrict the
 17 ability of prehospital emergency medical care personnel, under
 18 any other statute or regulation, to administer epinephrine, including
 19 the use of epinephrine auto-injectors, or to require additional
 20 training or certification beyond what is already required under the
 21 other statute or regulation.

22 SEC. 4. No reimbursement is required by this act pursuant to
 23 Section 6 of Article XIII B of the California Constitution because
 24 the only costs that may be incurred by a local agency or school
 25 district will be incurred because this act creates a new crime or
 26 infraction, eliminates a crime or infraction, or changes the penalty
 27 for a crime or infraction, within the meaning of Section 17556 of
 28 the Government Code, or changes the definition of a crime within
 29 the meaning of Section 6 of Article XIII B of the California
 30 Constitution.